

NOV - 4 1996

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE
E2590-B & E2590-N ARGON ACCESSORIES**

The E2590-B & E2590-N Argon Accessories are intended for use in open surgical procedures where argon-enhanced monopolar electrosurgery is desired.

The E2590-B & E2590-N Argon Accessories are sterile, single use, fixed electrode devices which allow for the introduction of argon gas around the electrosurgical electrode of an electrosurgical pencil. The Argon Accessories are designed for use with the following Valleylab Handswitching Pencils: E2515 & E2516, E2525, E2550 & E2555.

The biological safety of the E2590-B & E2590-N Argon Accessories has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility.

The E2590-B & E2590-N Argon Accessories have been designed to conform with the applicable sections of, IEC 601-1 (1988), Medical Electrical Equipment Part 1: General Requirements for Safety, IEC 601-2-2 (1991), Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment, and ANSI/AAMI HF18 (1993), Electrosurgical Devices.